IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:			
Timothy W. CONNER *et al.*		Art Unit:	1631
Appln. No.:	09/540,234	Examiner:	Shubo ZHOU
Filed:	April 3, 2000	Atty. Docket:	38-21(15726)B
Title:	***Nucleic Acid Molecules and Other Molecules Associated with Plants***		

#15 Plunkett 10/9/02 1663

APPELLANT'S BRIEF

Commissioner for Patents
Washington, DC 20231

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-identified patent application. A Notice of Appeal was filed on July 3, 2002. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

The Appellant is unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1 and 2 are pending. Claim 1 is independent. Claims 1 and 2 stand finally rejected under 35 U.S.C. §§ 101 and 112, first and second paragraphs. Applicants appeal all of the rejections of claims 1 and 2.

4. Status of Amendments

Applicants filed one Amendment (the "Amendment") subsequent to the Final Office Action mailed April 5, 2002 (Paper No. 8) ("Final Action"), in this case. The Amendment was entered, per the Advisory Action mailed September 19, 2002 (Paper Number 13) ("Advisory Action").

In the Final Action, the Examiner objected to the disclosure of the specification "because it contains an embedded hyperlink and/or other form of browser-executable code." Final Action, at page 2. Applicants amended the specification and believe the amendment obviates this objection.

Applicants additionally amended claim 1 in the Amendment. Applicants believe the amendment to claim 1 clarifies the issues on appeal with respect to the rejection of claims 1 and 2 under 35 U.S.C. § 112, second paragraph, as described in more detail *infra*.

5. Summary of Invention

The invention is directed to a nucleic acid molecule that encodes a plant protein or fragment thereof comprising the nucleic acid sequence of SEQ ID NO: 1. Specification at page 9, line 24 through page 10, line 3. The present invention is also directed to a nucleic acid molecule encoding a wheat protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1. *Id.*

6. Issues

The issues on Appeal are:

(a) whether claims 1 and 2 are unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by a specific asserted utility or a well established utility;

(b) whether claims 1 and 2 are unpatentable under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement because the claimed invention purportedly lacks utility;

(c) whether claims 1 and 2 are unpatentable under 35 U.S.C. § 112, first paragraph, for alleged insufficiency of written description;

(d) whether claims 1 and 2 are unpatentable under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement because undue experimentation would supposedly be required to make and/or use the claimed nucleic acid molecules; and

(e) whether claims 1 and 2 are unpatentable under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Grouping of Claims

Claims 1 and 2 remain in this case. Claim 2 depends from claim 1. The patentability of claims 1 and 2 is addressed in Sections 8.A through 8.F below. A copy of the currently pending claims is attached hereto as Appendix A.

8. Argument

A. Summary of Applicants' Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility . . . where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have disclosed nucleic acid molecules which, in their current

form, provide at least one specific benefit to the public, for example, the ability to identify the presence or absence of a polymorphism in a population of wheat plants. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acid molecules provide at least this benefit, they satisfy the utility requirement of 35 U.S.C. § 101. In addition, because the specification teaches how to make and use the claimed nucleic acid molecules for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Applicants have asserted that the claimed nucleic acid molecules actually work for that and other utilities disclosed and described in the specification, and so both enablement rejections must be reversed. Applicants have asserted that one skilled in the art is able to use the claimed nucleic acid molecules for at least two disclosed utilities, namely use to identify the presence or absence of a polymorphism and use as a hybridization probe for expression profiling. *See, e.g.,* specification at page 41, line 18 through page 48, line 21 and page 40, line 9 through page 41, line 17. The law clearly establishes that the enablement requirement is satisfied if at least one mode of making and using the invention is enabled. Because Applicants have asserted that the claimed nucleic acid molecules work for the disclosed utilities, and because one of skill in the art would understand how to make and use the invention commensurate with the scope of the claims, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Applicants have provided an adequate written description of the claimed nucleic acid molecules that demonstrates Applicants' possession of the claimed invention. The genera of claimed nucleic acid molecules, *i.e.*, the genus of nucleic acid molecules comprising the nucleic acid sequence of SEQ ID NO: 1, has been described by the recitation of a structural feature, *e.g.*, the nucleotide sequence of SEQ ID NO: 1, which distinguishes molecules in the claimed genera from molecules not in the claimed genera. Because the specification demonstrates that Applicants had possession of the invention, and have provided an adequate

description of the claimed genus of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112, first paragraph.

Finally, a person of ordinary skill in the art would understand the metes and bounds of the claims when read in light of the disclosure of the specification. The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Because Applicants have distinctly claimed the subject matter which they regard as their invention, the requirement of 35 U.S.C. § 112, second paragraph, has been met.

B. The Claimed Nucleic Acids Have Legal Utility

Pending claims 1 and 2 were erroneously rejected under 35 U.S.C. § 101 as allegedly not supported "by either a specific asserted utility or a well-established utility." Final Action at page 3. Although the Examiner has acknowledged that the specification identifies that the claimed nucleic acid molecules can be used to isolate genes in wheat and to isolate molecular markers, the Examiner contends these are non-specific uses because "the disclosed uses of these nucleic acids are not specific and are generally applicable to any nucleic acid." Office Action mailed October 23, 2001 (Paper Number 5), at pages 4-5. In addition, the Final Action asserts that the list of utilities "is simply a summarization of modern biotechnology." Final Action at page 3.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide <u>one</u> identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir.

1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip*, 185 F.3d at 1366, 51 USPQ.2d at 1702. For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicants have asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example, use to identify the presence or absence of a polymorphism and use as a hybridization probe for expression profiling. Specification at page 40, line 9 through page 48, line 21. Either of these utilities described alone is enough to satisfy 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and because they have done so in the present case, the premise of the rejection under 35 U.S.C. § 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

The Examiner acknowledges that the instant specification describes multiple utilities for the present invention, including use of the nucleic acid molecules for "isolating more genes in wheat, isolating molecular markers, etc." (citations omitted). Office Action mailed October 23, 2001, at page 5. The specification also discloses additional utilities for the claimed nucleic acid

molecules,[1] including introduction of the claimed nucleic acid molecules into a plant or plant cell (either as sense or antisense inhibitors), which can then be used to screen for compounds such as a herbicide or for traits such as disease resistance. Specification at page 81, line 10 through page 83, line 23. For example, a compound can be provided to both an antisense plant and a control plant (no antisense) and the effect of the compound on the plant can be monitored. Such a screen is analogous to a cell-based assay, which has a legally sufficient utility.[2] Thus, the use in such a screen of a plant or plant cell having an introduced claimed nucleic acid molecule is a legally sufficient utility. Other utilities disclosed in the specification include use of the claimed nucleic acid molecules to measure the level of mRNA in a sample,[3] in addition to their use as molecular markers.[4] *See, e.g.*, specification at page 40, line 24 to page 41, line 17 and page 25, line 13 through page 26, line 2.

(a) Identifying the Presence or Absence of a Polymorphism

One of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 41, line

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[1] It is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicants are not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.

[2] *See, e.g.*, MPEP § 2107.01 at page 2100-32.

[3] It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest, *e.g.*, drought stress. Contrary to the Examiner's assertions, this use is not using the claimed nucleic acid molecules to identify a " 'real world' context for use." *See* Office Action mailed October 23, 2001, at page 5. It is a **use** of the claimed nucleic acid molecules in a real world context.

[4] One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

18 through page 48, line 21. The Examiner argues that this utility, like all of the asserted utilities, is not specific or substantial, but does not provide any support (legal or factual) for the proposition that detection of polymorphisms is not a legal utility. *See* Office Action mailed October 23, 2001, at pages 5-6, Final Action at page 3.

Many of the disclosed utilities in this case, including the detection of polymorphisms, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates such utilities by asserting that these utilities are "neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds." Office Action mailed October 23, 2001, at page 5. However, the fact that a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107 at page 2100-33.

Use of the claimed nucleic acid molecules to detect the presence or absence of a polymorphism is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.[5] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of

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[5] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules or Source for Primers

Additional uses for the claimed nucleic acid molecules are as a probe for other molecules, and as a source of primers. The Examiner suggests that these uses are not legal utilities because "[t]he instant specification fails to link any utility specifically to the elected polynucleotide. ...simply acquiring a gene is not a real world utility." Final Action at page 3. This is not correct. The specification discloses that the claimed nucleic acid molecules can be used, via hybridization, in real world applications such as to isolate nucleic acid molecules of other plants and organisms such as alfalfa, *Arabidopsis*, *Brassica*, barley, wheat, oat, rice, etc.[6] Specification at page 37, line 25 through page 38, line 12. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and thus has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

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[6] Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicants to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

One illustrative example of a molecule that can be isolated using the claimed nucleic acid molecules is the promoter of the gene corresponding to that claimed nucleic acid molecule. Further, Applicants have specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk. Specification at page 39, line 9 through page 40, line 2. The Examiner denigrates that utility when he asserts that the disclosed utilities are "generic in nature and applicable to a myriad of such compounds." Office Action mailed October 23, 2001, at page 5.

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose, *i.e.,* chromosome walks. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, it is factually incorrect that this use is not "specific" to the claimed nucleic acid molecules. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate a promoter active in *Triticum aestivum*. Specification at page 33, line 24 to page 37, line 24. Random nucleic acid molecules are not similarly suitable. Furthermore, even if a random nucleic acid molecule provided a <u>better</u> starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing devices but

nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

The Final Action also appears to assert that the disclosed uses are legally insufficient because they are not "substantial" utilities. Final Action at page 3. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). "'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[7]

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, *e.g.*, to detect the presence or absence of polymorphisms. One example of the detection of polymorphisms providing an immediate benefit to the public is that it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a

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[7] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (CCPA 1974).

plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter and has attributed "real world" value to such nucleic acid molecules. The utility of ESTs is not merely an academic issue; the real world value of ESTs is self-evident from the growth of a multi-million dollar industry in the United States premised on the usefulness of ESTs. Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (C.C.P.A. 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Cf. Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of ESTs is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 2107 at 2100-29. Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[8] A challenge to the credibility of a utility is essentially a challenge directed to

[8] Examples of incredible utilities are given in MPEP § 2107 at page 2100-34, and include:

operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 2107.02 at 2100-40.

Applicants have explicitly identified specific and substantial utilities, not only in the specification, but in Applicants' Response dated January 23, 2002, at page 3. "To violate [35 U.S.C. §] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1 and 2 under 35 U.S.C. §101 is improper and should be reversed.

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an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

C. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has been challenged. Claims 1 and 2 were erroneously rejected under 35 U.S.C. § 112, first paragraph as allegedly not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action at page 4. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection is improper and should be reversed. *See, In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q. 2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (B.P.A.I. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

D. The Specification Provides An Adequate Written Description of the Claimed Invention

Despite the Examiner's admission that the specification describes SEQ ID NO: 1, the adequacy of the written description has been challenged by the Examiner because the nucleic acid molecules of claims 1 and 2 allegedly lack "written description in the specification in such a way as to enable one skilled in the art to which it pertains, or with which is most nearly connected to, to make and/or use the invention." Final Action at page 4. The basis for the Examiner's challenge is that "the claimed invention is a genus whose members have substantial variability because of the claim language of 'comprising' and 'fragment', one of skilled [sic] in the art would not know what features distinguish the members of the genus from non-members." Final Action at page 5. This is not a proper basis for a written description rejection of a "comprising" claim. If it was, every "comprising" claim ever written would be invalid for failing

to describe every nuance of the claimed invention. Furthermore, the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed genera of nucleic acid molecules.

(1) The Specification Reflects Applicants' Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if every nuance of the invention was not expressly described, then the written description requirement has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. After reading the present specification, a person of ordinary skill in the art, *e.g.*, a molecular biologist, would understand that Applicants had possession of nucleic acid molecules comprising SEQ ID NO: 1 and, therefore, had possession of the claimed invention.

Applicants have provided the nucleotide sequence required by the claims, *i.e.*, SEQ ID NO: 1, as well as, for example, vectors comprising the nucleic acid sequence (*see, e.g.*, specification at page 64, line 20 through page 65, line 13). The fact that the claims at issue are intended to cover molecules that include the recited sequence joined with additional sequences does not mean that Applicants were any less in possession of the claimed nucleic acid molecules.[9] It is well-established that use of the transitional term "comprising" leaves the claims

[9] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498,

"open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

The present application describes more than just the nucleotide sequence required by the claims (SEQ ID NO: 1). For example, it describes vectors comprising the claimed nucleic acid molecules (*See* specification at page 65, line 9 through page 72, line 11) and describes how to make the nucleotide sequences and the libraries from which they were originally purified (*See* specification at page 1, line 14 through page 3, line 21, and Examples 1-5). Furthermore, the addition of extra nucleotides or detectable labels to the claimed nucleotide sequence (SEQ ID NO: 1) is readily envisioned by one of ordinary skill in the art upon reading the present specification.[10] *See, e.g.*, specification at page 17, lines 22-26 (describing sequences with labels to facilitate detection), page 29, line 18 through page 30, line 14 (describing fusion peptide molecules encoded by the claimed nucleic acid molecules), page 60, line 8 through page 61, line 2 (describing site-directed mutagenesis) and page 84, line 22 through page 85, line 3 (citing references describing the construction, manipulation and isolation of nucleic acid macromolecules). Moreover, it is well established that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981)).

1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

[10] It is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

(2) Applicants Have Described the Claimed Invention

The Final Action asserts that "applicants fail to point out what features distinguishing [sic] the members of the claimed genus from non-members." Final Action at page 5. The Examiner appears to assert that each nucleic acid molecule within the claimed genus must be described by its complete structure. These assertions are totally unfounded. The Federal Circuit has elucidated a test for written description whereby a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description.

In particular, Applicants have disclosed common structural features, for example, the nucleotide sequence of SEQ ID NO: 1. The respective common structural feature (the nucleotide sequence of SEQ ID NO: 1) is shared by every nucleic acid molecule in the claimed genus, and it distinguishes the members of the claimed genus from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1. If a nucleic acid molecule does not contain SEQ ID NO: 1, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 1 or it does not. One skilled in the art would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. Thus, claims 1 and 2 satisfy the written description requirement of 35 U.S.C. § 112.

The Examiner asserts, in the Final Action, that "one amino acid residue constitutes a fragment of a plant protein, which is part of the claim limitation. If this is the case, how could the instant invention i.e., one amino acid residue, distinguish from the non-members, which can

be also one amino acid residue." Final Action at page 5. This interpretation of the claims and the Examiner's application of the written description requirement cannot be supported.

Claims 1 and 2 are directed to nucleic acid molecules which encode a plant protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1. In rejecting claim 1 under 35 U.S.C. § 112, first paragraph, the Examiner has apparently applied an untenable interpretation of the claims to cover fragments of the specifically claimed nucleic acid molecule, rather than a fragment of a plant protein.

A grammatically consistent interpretation of the claims at issue, however, would relate the phrase "or fragment thereof" in the preamble back to the phrase "plant protein" directly preceding it. Further, because the phrase "or fragment thereof" appears before the transition phrase "comprising", it is clear that it does not refer to a fragment of SEQ ID NO: 1. Rather, the claimed nucleic acid molecules must have a nucleic acid sequence comprising SEQ ID NO: 1 and also must encode a plant protein or fragment thereof. Hence, the interpretation of the claims by the Examiner to encompass a single amino acid residue is inaccurate and misapplies the requirements of § 112, first paragraph.

For the reasons stated above, claims 1 and 2 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Thus, the rejection is improper and should be reversed.

E. The Specification is Enabling for the Scope of the Claimed Nucleic Acid Molecules

Claims 1 and 2 were erroneously rejected as not being enabled by the specification. The Examiner admits that the specification is enabling for polynucleotides and nucleic acids of SEQ ID NO: 1, however, the Final Action asserts the specification "does not reasonably enable nay [sic] person skilled in the art ...to make and use the invention commensurable [sic] in scope with these claims." Final Action at page 5.

The Examiner cites no support for the proposition that the full scope of the claims would require undue experimentation by one of ordinary skill in the art to make or use the claimed invention. Furthermore, in view of the Examiner's admission that SEQ ID NO: 1 is enabled, and the well established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques" (*see, for example, Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000)), which would include the use of the claimed sequence with other nucleic acid sequences, Applicants submit the Examiner has not met the required burden. Applicants further assert that the use of the transitional phrase "comprising", which leaves the claims "open for the inclusion of unspecified ingredients even in major amounts" (*Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986)) is well established in patent jurisprudence.

The Final Action attempts to abrogate the Examiner's burden to present evidence that the claims are not enabled by arguing that the claimed invention, *i.e.* nucleic acids comprising or having the sequence of the elected SEQ ID NO: 1, is a genus "whose members have substantial variability". Final Action at page 5. In response, Applicants submit that an analysis of the criteria presented by *In re Wands* supports Applicants' position that no undue experimentation would be required to make and use the claimed invention. *See In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1998).

The first *Wands* criterion is the quantity of experimentation necessary. The "make-and-test" quantum of experimentation is reduced by the extensive knowledge, *e.g.*, of conservative nucleotide substitutions, identification of an active site, and radiometric synthase assay conditions, to which a person of ordinary skill in the art has access. Performing routine and well-known steps, such as sequence alignment protocols, molecular weight determination, and

antibody hybridization assays, cannot create undue experimentation even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 218-219 (C.C.P.A. 1976).

The second and third *Wands* criteria relate to the amount of direction or guidance given, and the presence or absence of working examples. Again, the specification provides evidence of sequence identity, discloses start and stop positions within a sequence, and discusses the use of the claimed SEQ ID NO to isolate additional sequences within a genome and to create cDNA libraries. *See, e.g.,* specification at page 37, line 25 through page 38, line 12, Examples 1-6 and the sequence listing. Based on such disclosure, one of ordinary skill in the art would be enabled to make and use the invention commensurate in scope with the claims.

The fourth, fifth, and sixth *Wands* criteria focuses on the nature of the invention, the state of the art, and the relative skill in the art. The present invention relates to nucleic acid sequences, and the specification further describes amino acid sequences derived therefrom, antibodies, constructs and methods related thereto. *See, e.g.,* specification 28, line 26 through page 30, line 14 (describing polypeptide molecules and homologues) and page 64, line 20 through page 81, line 15 (describing use of the claimed nucleic acid molecules in methods of transforming plants). Practitioners in this art are guided by considerable knowledge and resources on the conditions and approaches that can be utilized to identify, confirm, and introduce into other hosts, nucleic acid and amino acid sequences.

The seventh criterion considers the predictability of the art. While the Final Action admits that the specification is "enabling for polynucleotide of the SEQ ID NO: 1", it alleges that this is not enabling for the full scope of the claims because "the claimed invention is a genus whose members have substantial variability". Final Action at page 5. Applicants respectfully disagree and assert, as discussed *supra*, that the specification discloses sufficient guidance to render the results of substitutions, additions, and deletions within the claimed SEQ ID NO predictable. *See,* for example, page 19, line 17 through page 25, line 13.

The eighth criterion focuses on the breadth of the claims. Enablement is satisfied when the disclosure "adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility". *See In re Vaeck,* 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). In the present case, one of skill in the art is specifically guided by the disclosure to look to, *e.g.*, sequence identity data in making that determination.

The Examiner has presented no evidence supporting the allegation that one of ordinary skill in the art would not be able to make or use the claimed nucleic acid molecules in light of Applicants' disclosure. Furthermore, the analysis of the Wands factors, discussed *supra*, conclusively establishes that one of ordinary skill in the art would be able to make and use the claimed invention based on the disclosure in the specification. Accordingly, for at least these reasons, the enablement rejection under 35 USC § 112, first paragraph, is improper and must be reversed.

F. The Claims Particularly Point Out and Distinctly Claim the Subject Matter Which Applicants Regard as Their Invention

The Examiner erroneously rejected claims 1 and 2 "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Final Action at page 6. According to the Examiner, the phrase "a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1" is vague and confusing. Final Action at page 6.

In the Amendment filed September 10, 2002, Applicants deleted this language from claim 1. The Amendment was entered by the Examiner as shown in the Advisory Action. Thus, Applicants believe the basis for this rejection has been overcome by the entry of the Amendment and, as such, the rejection under 35 U.S.C. § 112, second paragraph, is rendered moot and should be withdrawn.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

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APPENDIX A

1. A substantially purified nucleic acid molecule that encodes a plant protein or fragment thereof comprising the nucleic acid sequence of SEQ ID NO: 1.

2. The substantially purified nucleic acid molecule according to claim 1, wherein said plant protein or fragment thereof is a wheat protein or fragment thereof.